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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,554	01/23/2006	Keijitsu Tanaka	Q91757	2075
23373 7590 03/31/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER SHAHNAN SHAH, KHATOL S				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 03/31/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/565,554

Applicant(s)

TANAKA ET AL.

Examiner

Khatol S. Shahnan-Shah

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2 and 4-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Amendment

1. Applicants' response of 01/04/2010 is acknowledged.

Rejection(s) Maintained

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Rejection of claims 9 and 11-18 are rejected under 35 U.S.C. 103(a), made in paragraph 4 of the office action mailed 7/02/2009 is maintained.

The rejection was as stated below:

Claims 9 and 11-18 are rejected under 35 U.S.C. 103(a) as being obvious over Clausen et al. (US 5, 563040) in view of Hirano et al. (Journal of Wood

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Science, vol, 46, 2000) Prior art of record applicants' 1449. and further in view of Khowala et al. US 6,946,277 B2

Claims 9 and 11-16 are drawn to an agent used for diagnosing wood decay which comprises an antibody obtained by sensitizing an animal with an antigen which is a protein having a molecular weight of 1000-100,000 obtained by culturing a wood destroying fungi, claims 17-18 are drawn to a dot blot kit for diagnosing decay in wood.

Clausen et al. teach an agent used for diagnosing wood decay which comprises an antibody obtained by sensitizing an animal with an antigen which a protein is obtained by culturing a wood destroying fungus (see abstract and claims). Clausen et al. teach brown rot fungus *Postia placenta* from family Basidiomycetes (see column 3), sensitizing an animal with an antigen and production of monoclonal and polyclonal antibodies (see example 1 and claims). Clausen et al. teach other fungi *Gloeophyllum trabeum*, *Coniophora puteana* and *Serpula* species (see column 7). Clausen et al. teach limitation of claims 17-18 a diagnostic kit having a polyester cloth device and a capture zone for the substrate (see claims 12-14). Clausen et al. do not teach specifically a molecular weight of 1000-100,000 or *Fomitopsis palustris*. These deficiencies are overcome by the teachings of Hirano et al.

Hirano et al. teach a fraction containing low molecular weight purified protein from cultures of brown rot fungus *Tyromyces palustris* (i.e. *Fomitopsis palustris*, new name) see abstract. Polyclonal antibodies raised to the fraction were used for immunogold labeling of spruce (see page 45). Hirano et al. teach culture conditions; preparation of protein fraction, preparation of polyclonal antibodies; immunoblotting and ELISA (see pages 46-47). Hirano et al. do not teach

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specifically cellobiose as the main carbon source. This deficiency is overcome by the teachings of US 3, 677,899.

Khowala et al. teach cellobiose as the main carbon source for culturing fungi (see claims specially claim 2 and column 5, lines 27-45)

Therefore, it would have been obvious to one of ordinary skill in the art to use the *protein* as taught by Hirano et al. in the assay of Clausen et al. and use the liquid medium taught by Khowala et al. to provide the claimed invention, since as taught in Clausen et al. numerous modification and embodiments devised by those skilled in art other than the ones specifically described above, may be employed to detect the presence of the suspected antigens. For instance antibodies for other components or other groups of fungi can alternatively be used in this invention (see column 5). As to specific temperatures and molecular weights, using different temperatures and molecular weights would have been considered optimization of experimental parameters and would be obvious to one of ordinary skill in the art. As to the limitation not reactive with other fungi it would be obvious to one of ordinary skill in the art to provide antibodies specific to wood decay fungi.

Applicant's arguments of 01/04/2010 have been fully considered but they are not persuasive.

Applicant argues that:

- The Office Action fails to set forth a reason that would have prompted a person of ordinary skill to culture the fungi of Hirano *et al.* in a medium containing cellobiose as the main carbon source. First, Applicants again respectfully point out that relevant law holds that it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Further still, a *prima facie* case of obviousness cannot be maintained if one of ordinary skill in the art would not have

possessed at least a reasonable expectation of success in making such a combination. In this regard, Applicants respectfully submit that the outstanding obviousness rejection over Clausen *et al.*, Hirano *et al.* and Khowala *et al.* suffers from the same deficiencies as the previous rejection of record over Clausen *et al.*, Hirano *et al.* and Kawai *et al.*, namely in that the rejection fails to proffer a reason that would credibly have prompted a person of ordinary skill in the relevant field to culture the fungi of Hirano *et al.* in a medium in which cellobiose is the main carbon source. Specifically, as acknowledged by the Examiner, column 5 of Clausen *et al.* provides merely a *generic* suggestion that "numerous modifications and embodiments devised by those skilled in the art, other than the ones described above, may be employed to detect the presence of the suspected antigen." However, this generic suggestion, in itself, clearly provides no credible reason or motivation that would have prompted a person of ordinary skill in the relevant field to use cellobiose as the major carbon source in the method of Hirano *et al.*, as is required to sustain the rejection. Indeed, while the Examiner attempts to impart some specificity

- In view of the unrelated disclosures of Hirano *et al.* and Khowala *et al.* one of ordinary skill would not have possessed sufficient motivation to combine the cited references. Second, and independent of the above arguments, Applicants respectfully submit that one of ordinary skill in the art would not have possessed sufficient reason or motivation to employ a medium containing cellobiose as the major carbon source in the method of Hirano *et al.*, in view of the substantially disparate disclosures of Hirano *et al.* and Khowala *et al.* For example, in the portion of Khowala *et al.* relied upon to make the rejection, namely column 5, lines 27-45, Khowala *et al.* discloses the use of D-cellobiose with succinate as a main carbon source for culturing *Termitomyces clypeatus* solely for the purpose of enhancing the secretion of cellobiase into the culture medium; as discussed in column 6, lines 23-28, cellobiose is employed because it produces high cellobiase

activity in the culture medium when a glycosylation inhibitor (i. e., 2-deoxy-D-glucose) is also present.

- One of ordinary skill in the art would not have possessed a reasonable expectation of success in modifying the method of Hirano *et al.* to use cellobiose as the main carbon source. Third, and independent of the above arguments, Applicants respectfully submit that the presently claimed invention is nonobvious over the cited references at least because one of ordinary skill in the art would not have possessed a reasonable expectation of success in employing cellobiose as the main carbon source in the method of Hirano *et al.*, as is required of obviousness. For example, in the paragraph bridging columns 1 and 2 of page 45, Hirano *et al.*, citing to Enoki *et al.* as support, states that "the rates of [hydroxyl radical] production in cultures of brown-rot fungi, including *Tyromyces palustris*, are directly proportional to the degradation rates of wood, crystalline cellulose, and lignin substructure model compounds." (Emphasis added.) Enoki *et al.* demonstrates the inducibility of these hydroxyl radicals, through the inducibility of the low-molecular weight proteins of Hirano *et al.*, in response to specific substrates. For example, Enoki *et al.*, using ethylene production as an indicator of oxidant production, discloses that if 7". *palustris* is cultured in a medium using glucose as a carbon source, or glucose in combination with either lignin or cellulose, neither cellulose or lignin degradation occurs, nor does ethylene production (see Table 2), demonstrating that hydroxyl production is not induced in these samples; Table 3 directly confirms the correlation between hydroxyl radical production by *T. palustris* (the focus of Hirano *et al.*) and ethylene production, because ethylene production by *T. palustris* was markedly suppressed by the addition of the hydroxyl radical scavengers DMNA and guaiacol. In contrast, however, as demonstrated in Table 2 of Enoki *et al.*, oxidant production by *T. palustris* was only induced when beech wood was present in the culture medium, suggesting that the low-molecular

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weight proteins catalyzing hydroxyl radical production are specifically induced in the presence of only wood, and not glucose, lignin or cellulose. It is well-settled that in any obviousness inquiry, the person of ordinary skill in the art is a hypothetical person who is presumed to have known the *relevant* art at the time of the invention.

In response to applicants' arguments it is this office's position that under the TSM test, a claimed invention is obvious when there is a teaching, suggestion or motivation to combine prior art teachings. The teaching, suggestion or motivation may be found in the prior art, in the nature of the problem, **or in the knowledge of a person having ordinary skill in the art.** According to supreme court on KSR International Co. v. Teleflex Inc. 82 USPQ2d 1385, 1396 (2007), the TSM test is one of a number of valid rationales that could be used to determine obviousness. **It is not the only rationale that maybe relied upon to support a conclusion of obviousness.**

In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596

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(Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, **it would have been obvious to one of ordinary skill in the art** to use the *protein* as taught by Hirano et al. in the assay of Clausen et al. and use the liquid medium taught by Khowala et al. to provide the claimed invention, since as taught in Clausen et al. numerous modification and embodiments devised by those skilled in art other than the ones specifically described above, may be employed to detect the presence of the suspected antigens. For instance antibodies for other components or other groups of fungi can alternatively be used in this invention (see column 5). As to specific temperatures and molecular weights, using different temperatures and molecular weights would have been considered optimization of experimental parameters and would be obvious to one of ordinary skill in the art. As to the limitation not reactive with other fungi it would be obvious to one of ordinary skill in the art to provide antibodies specific to wood decay fungi. As to using cellobiose as a carbon source in a culture medium for fungi, this is well known in the art of culturing fungi as evidenced by Lesage-Meessen et al. US 5,866,380 and Khowala et al. Lesage-Meessen et al. teach culture media comprising cellobiose at a concentration between 0.5g/l and 10g/l (see column 4 and claim 11). Lesage-Meessen et al. media containing other oligosaccharides and polysaccharides (see column 4). Applicants' specification pages 10 and 11 teach that culturing is conducted by using a liquid medium. Examples of the culture medium usable therein include various kinds of liquid media; however, particularly preferred is a medium containing cellobiose or containing oligosaccharide or polysaccharide which can produce cellobiose through metabolism.

Furthermore, one of ordinary skill in the art would have "reasonable expectation of success" to use cellobiose at a concentration between 0.5g/l and 10g/l as carbon sources to induce different molecular weight proteins in the culture.

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In response to applicants' argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., using beech wood as Enoki et al.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

4. No claims are allowed.
5. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure.

Lesage-Meessen et al. US 5,866,380.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thur-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on (571)-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/
Examiner, Art Unit 1645
March 25, 2010

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

